K090620

APR - 8 2009

510(k) Summary

Trade Name:	QuikClot® Interventional™ hemostatic bandage
Device Class:	Unclassified
Classification Panel:	General and Plastic Surgery
Classification Name:	Dressing
Classification Code:	FRO
Predicate Device(s):	QuikClot® eX™ (K072474) D-Stat Dry™ Hemostatic Bandage (K061219) ChitoFlex-Surgical dressing (K080818)
Submitted By:	Ronald E. Peterson, Dir. of QA and Regulatory
Company Name:	Z-Medica Corporation
Company Address:	4 Fairfield Blvd., Wallingford, CT 06492
Company Phone:	+1-203-294-0000 x262
Prepared:	March 5, 2009

Description of Device

QuikClot® Interventional™ hemostatic bandage is a kit that consists of a hemostatic pad and an adhesive bandage. The adhesive bandage is a 3M Tegaderm® 4" x 4-3/4" bandage (reference K973036). The hemostatic pad is a hemostatic dressing made of soft, white, kaolin impregnated gauze, configured in a 1 ½" long by 1 ½"wide by ½" thick multi-layer pad. The pad is held secured in place by stitching with polyester thread. QuikClot® Interventional™ hemostatic bandage is packaged in a plastic tray within a peelable foil pouch and irradiated to a SAL of 10^{-6}.

Intended Use of Device

Prescription Use: QuikClot® Interventional™ hemostatic bandage is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 12 Fr.

Discussion of Data to Support Substantial Equivalence

In pre-clinical porcine model testing, QuikClot® Interventional™ hemostatic bandage has demonstrated hemostasis following the removal of percutaneous vascular access catheters. The dressing successfully controlled all bleeding following 25 vascular access procedures when either an 8French or a 12French tissue dilator was used. QuikClot® Interventional™ hemostatic bandage controlled bleeding as effectively as the ChitoFlex-Surgical dressing and the D-Stat Dry™ Hemostatic Bandage predicate devices. QuikClot® Interventional™ hemostatic bandage is composed of identical materials as the QuikClot® eX™ device, therefore the successful biocompatibility testing for QuikClot® eX™ device (MEM Elution, Kligman Maximization, and Intracutaneous Injection) also applies to the QuikClot® Interventional™ hemostatic bandage.

Conclusion

Based on the in-vivo test data and the device description, the QuikClot® Interventional™ hemostatic bandage is substantially equivalent in indications for use and technology to the predicate devices (QuikClot® eX™ (K072474), D-Stat Dry™ Hemostatic Bandage (K061219) and ChitoFlex-Surgical dressing (K080818)).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2009

Z-Medica Corporation
% Mr. Ronald E. Peterson
Director of Quality Assurance and
Regulatory
4 Fairfield Boulevard
Wallingford, Connecticut 06492

Re: K090620
Trade/Device Name: QuikClot® Interventional™
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 5, 2009
Received: March 9, 2009

Dear Mr. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

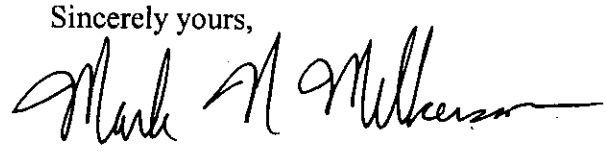
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090620

Device Trade Name: QuikClot® Interventional™

Indications for Use:

QuikClot® Interventional™ hemostatic bandage is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 12 Fr.

Prescription Use ☑ AND/OR Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090620